7

Zantac syrup

These yellowing pages
from my own file
show I was the
nearest to being an
insider

Dave
30/1/87

DEFENDANT'S EXHIBIT
6 Feb. 1997 VID

GLAXO WELCOME INC. AND GLAXO GROUP LIMITED v. PHARMEDIUM CORPORATION
CIVIL ACTION NO. AND 96-465 HIGHLY CONFIDENTIAL UNDER PROTECTIVE ORDER

Y010984

PLAINTIFF'S TRIAL EXHIBIT 242

JMr, MMC, IKW, IK, J~, DL, DEwad, A.Daunt, M.Zu.., J.....

Zantac Syrup Options as I see them 16/8/85

UK ① Launch c 4° storage restriction
Adv. Earliest launch
Disadv. less convenient to use
May get ranitidine undeserved reputation for instability

② Check EtOH is OK — can we lower it?
- medically
- stability ← 2-3 weeks.

Check whether EtOH + protein or market form?

③ If EtOH OK put up stability batches
Say mid Sept
3m take off + analysis = early Jan
Target ISC tight for Jan O.K for Feb 86

USA Either ① Put in NDA as is with 4° storage restriction
② Advise Glaxo = that formula is O.K for creamer pack

or Put EtOH formulation on stability (would need more bottles / cap esp PET).

done.

- Chlorhexidine ?? Try to kill it. ICI oral toxicity.
- Phenoxyethanol it is designed to kill Ps cep. Unknown action pH7.
(Look 80° / 10 min

- Look at 2 levels. Taste? Solubility? Add to
Benzalk. conc | Taste ① | Micro ② | Analytical ③ | Stringiness ④ | Toxicity ⑤

Summary Propyl + Butyl formula =
5% Ethanol — prepared by AED 3% + 1%
Phenoxyethanol at two level 0.5 1.0
BKC — ... — (4 3-4 weeks)
4. when does phenol take yield 0.1% ?

how c PET get packs

GLAXO WELCOME INC. AND GLAXO GROUP LIMITED v. PHARMADYNE CORPORATION
CIVIL ACTION NO AND 96-455 HIGHLY CONFIDENTIAL UNDER PROTECTIVE ORDER

Y010985

CONFIDENTIAL UNDER PROTECTIVE ORDER G026881

~~CWAC~~ synf

4/10/85
JKLong

Points

1. Formulation proposed for marketing is effective against Ps cipacia when propyl and butyl are at check spec lower limit 70% provided 5% EtOH is included

2. EtOH 3% and EtOH 1% only partial preservation - do not hold

3. Need to check that EtOH 5% does not have significant effect on rate of hydrolysis of procaine or transesterifies (4 week 45° due 9th 11/10/85). If it does, we would have to avoid EtOH and go to phenoxyethanol (see 6).

4. Need confirmation that EtOH 5% is medically and commercially acceptable.

5. Need challenge at 4%, 4.5% EtOH with a check spec: 80-110%

6. The effect of ethanol concentration 5, 3, 1% is also seen with the preliminary (methyl, propyl and butylhydroxybenzoate) formulation and with ethyl, propyl and butylhydroxybenzoate formulation

7. Phenoxyethanol at acceptable conc: for tank, 0.25% w/v, is as effective as 5% EtOH when added to form proposed for marketing. ⇒ clinically acceptable = candidate without precedent for oral use but merely say this is because of lack

8. Phenol at acceptable conc: for tank 0.005% is ineffective

9. Returning to the methyl formulation but increasing the conc: to new spec: at 4° gives no improvement

- Do 7.5% : rate: / tank / clarity

GLAXO WELCOME INC. AND GLAXO GROUP LIMITED v. PHARMADYNE CORPORATION
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Y010986